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## **ENVIRONMENTAL PROTECTION AGENCY**

### **40 CFR Part 721**

**[EPA-HQ-OPPT-2018-0697; FRL-9986-83]**

**RIN 2070-AB27**

### **Significant New Use Rules on Certain Chemical Substances**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** EPA is proposing significant new use rules (SNURs) under the Toxic Substances Control Act (TSCA) for 28 chemical substances which were the subject of premanufacture notices (PMNs). The chemical substances are subject to Orders issued by EPA pursuant to section 5(e) of TSCA. This action would require persons who intend to manufacture (defined by statute to include import) or process any of these 28 chemical substances for an activity that is proposed as a significant new use to notify EPA at least 90 days before commencing that activity. The required notification initiates EPA's evaluation of the intended use within the applicable review period. Persons may not commence manufacture or processing for the significant new use until EPA has conducted a review of the notice, made an appropriate determination on the notice, and has taken such actions as are required with that determination.

**DATES:** Comments must be received on or before *[insert date 45 days after date of publication in the Federal Register]*.

**ADDRESSES:** Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2018-0697, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online

instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** *For technical information contact:* Kenneth Moss, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-9232; email address: [moss.kenneth@epa.gov](mailto:moss.kenneth@epa.gov).

*For general information contact:* The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: [TSCA-Hotline@epa.gov](mailto:TSCA-Hotline@epa.gov).

## **SUPPLEMENTARY INFORMATION:**

### **I. General Information**

#### *A. Does this Action Apply to Me?*

You may be potentially affected by this action if you manufacture, process, or use the chemical substances contained in this proposed rule. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather

provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Manufacturers or processors of one or more subject chemical substances (NAICS codes 325 and 324110), e.g., chemical manufacturing and petroleum refineries.

This action may also affect certain entities through pre-existing import certification and export notification rules under TSCA. Chemical importers are subject to the TSCA section 13 (15 U.S.C. 2612) import certification requirements promulgated at 19 CFR 12.118 through 12.127 and 19 CFR 127.28. Chemical importers must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA. Importers of chemicals subject to final SNURs must certify their compliance with the SNUR requirements. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. In addition, any persons who export or intend to export a chemical substance that is the subject of this proposed rule on or after *[insert date 30 days after date of publication in the **Federal Register**]* are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)) (see § 721.20), and must comply with the export notification requirements in 40 CFR part 707, subpart D.

*B. What Should I Consider as I Prepare My Comments for EPA?*

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so

marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at <http://www.epa.gov/dockets/comments.html>.

## **II. Background**

### *A. What Action is the Agency Taking?*

EPA is proposing these SNURs under TSCA section 5(a)(2) for chemical substances that were the subject of PMNs and are subject to Orders issued by EPA pursuant to section 5(e) of TSCA. These proposed SNURs would require persons to notify EPA at least 90 days before commencing the manufacture or processing of a chemical substance for any activity proposed as a significant new use. Receipt of such notices would allow EPA to assess risks that may be presented by the intended uses and, if appropriate, to regulate the proposed use before it occurs. Additional rationale and background to these proposed rules are more fully set out in the preamble to EPA's first direct final SNUR published in the **Federal Register** issue of April 24, 1990 (55 FR 17376). Consult that preamble for further information on the objectives, rationale, and procedures for SNURs and on the basis for significant new use designations, including provisions for developing test data.

### *B. What is the Agency's Authority for Taking this Action?*

Section 5(a)(2) of TSCA (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a "significant new use." EPA must make this determination by rule after considering all relevant factors, including the four bulleted TSCA section 5(a)(2) factors listed in Unit III. Once EPA determines that a use of a chemical substance is a significant new use, TSCA section 5(a)(1)(B) requires persons to submit a significant new use notice (SNUN) to EPA at least 90 days before they manufacture or process the chemical substance for that use (15

U.S.C. 2604(a)(1)(B)(i)). TSCA furthermore prohibits such manufacturing or processing from commencing until EPA has conducted a review of the notice, made an appropriate determination on the notice, and taken such actions as are required in association with that determination (15 U.S.C. 2604(a)(1)(B)(ii)).

### *C. Applicability of General Provisions*

General provisions for SNURs appear in 40 CFR part 721, subpart A. These provisions describe persons subject to the rule, recordkeeping requirements, and exemptions to reporting requirements. Provisions relating to user fees appear at 40 CFR part 700. According to § 721.1(c), persons subject to SNURs must comply with the same SNUN requirements and EPA regulatory procedures as submitters of PMNs under TSCA section 5(a)(1)(A). In particular, these requirements include the information submission requirements of TSCA section 5(b) and 5(d)(1), the exemptions authorized by TSCA section 5(h)(1), (h)(2), (h)(3), and (h)(5), and the regulations at 40 CFR part 720. Once EPA receives a SNUN, EPA must either determine that the significant new use is not likely to present an unreasonable risk of injury or take such regulatory action as is associated with an alternative determination before the manufacture or processing for the significant new use can commence. If EPA determines that the significant new use is not likely to present an unreasonable risk, EPA is required under TSCA section 5(g) to make public, and submit for publication in the **Federal Register**, a statement of EPA's findings.

### **III. Significant New Use Determination**

Section 5(a)(2) of TSCA states that EPA's determination that a use of a chemical substance is a significant new use must be made after consideration of all relevant factors, including:

- The projected volume of manufacturing and processing of a chemical substance.

- The extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance.

- The extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance.

- The reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

In addition to these factors enumerated in TSCA section 5(a)(2), the statute authorizes EPA to consider any other relevant factors.

To determine what would constitute a significant new use for the 28 chemical substances that are the subject of these SNURs, EPA considered relevant information about the toxicity of the chemical substances and potential human exposures and environmental releases that may be associated with the conditions of use of the substances, in the context of the four bulleted TSCA section 5(a)(2) factors listed in this unit.

#### **IV. Substances Subject to this Proposed Rule**

EPA is proposing significant new use and recordkeeping requirements for 28 chemical substances in 40 CFR part 721, subpart E. In this unit, EPA provides the following information for each chemical substance:

- PMN number.
- Chemical name (generic name, if the specific name is claimed as CBI).
- Chemical Abstracts Service (CAS) Registry number (if assigned for non-confidential chemical identities).
- Basis for the TSCA section 5(e) Order.
- Information identified by EPA that would help characterize the potential health and/or

environmental effects of the chemical substance in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use designated by the SNUR. This information may include testing required in a TSCA section 5(e) Order to be conducted by the PMN submitter, as well as testing not required to be conducted but which would also help characterize the potential health and/or environmental effects of the PMN substance. Any recommendation for information identified by EPA was made based on EPA's consideration of available screening-level data, if any, as well as other available information on appropriate testing for the chemical substance. Further, any such testing identified by EPA that includes testing on vertebrates was made after consideration of available toxicity information, computational toxicology and bioinformatics, and high-throughput screening methods and their prediction models. EPA also recognizes that whether testing/further information is needed will depend on the specific exposure and use scenario in the SNUN. EPA encourages all SNUN submitters to contact EPA to discuss any potential future testing. See Unit VII. for more information.

- CFR citation assigned in the regulatory text section of the proposed rule. The regulatory text section of each proposed rule specifies the activities that would be designated as significant new uses. Certain new uses, including exceedance of production volume limits (i.e., limits on manufacture volume) and other uses designated in this proposed rule, may be claimed as CBI.

These proposed rules include 28 PMN substances that are subject to Orders issued under TSCA section 5(e)(1)(A). Each Order is based on one or more of the findings in TSCA section 5(a)(3)(B): there is insufficient information to permit a reasoned evaluation; in the absence of sufficient information to permit a reasoned evaluation, the activities associated with the PMN substances may present unreasonable risk to health or the environment; the substance is or will

be produced in substantial quantities, and enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant (substantial) human exposure to the substance. Those Orders require protective measures to limit exposures or otherwise mitigate the potential unreasonable risk. The proposed SNURs would identify as significant new uses any manufacturing, processing, use, distribution in commerce, or disposal that does not conform to the restrictions imposed by the underlying Orders, consistent with TSCA section 5(f)(4).

Where EPA determined that the PMN substance may present an unreasonable risk of injury to human health via inhalation exposure, the underlying TSCA section 5(e) Order usually requires, among other things, that potentially exposed employees wear specified respirators unless actual measurements of the workplace air show that air-borne concentrations of the PMN substance are below a New Chemical Exposure Limit (NCEL) that is established by EPA to provide adequate protection to human health. In addition to the actual NCEL concentration, the comprehensive NCELS provisions in TSCA section 5(e) Orders, which are modeled after Occupational Safety and Health Administration (OSHA) Permissible Exposure Limits (PELs) provisions, include requirements addressing performance criteria for sampling and analytical methods, periodic monitoring, respiratory protection, and recordkeeping. However, no comparable NCEL provisions currently exist in 40 CFR part 721, subpart B, for SNURs. Therefore, for these cases, the individual SNURs in 40 CFR part 721, subpart E, will state that persons subject to the SNUR who wish to pursue NCELS as an alternative to the § 721.63 respirator requirements may request to do so under § 721.30. EPA expects that persons whose § 721.30 requests to use the NCELS approach for SNURs that are approved by EPA will be required to comply with NCELS provisions that are comparable to those contained in the



corresponding TSCA section 5(e) Order for the same chemical substance.

**PMN Numbers:** P-15-353 and P-15-433.

*Chemical Names:* Fatty acids, C16 and C18-unsaturated, methyl esters, chlorinated (P-15-353) and chlorinated complex esters (generic) (P-15-433).

*CAS Numbers:* 1642303-17-0 (P-15-353) and not available (P-15-433).

*Effective date of TSCA section 5(e) Order:* July 25, 2018.

*Basis for TSCA section 5(e) Order:* The PMNs state that the generic (non-confidential) use of the PMN substances will be as lubricant additives. Based on submitted analogue data, EPA has identified concern for irritation. Based on the physical/chemical properties of the PMN substances (as described in the New Chemical Program's PBT category at 64 FR 60194; November 4, 1999) and test data on structurally similar substances, the PMN substances are potentially persistent, bioaccumulative, and toxic (PBT) chemicals. EPA estimates that the PMN substances will persist in the environment for more than two months and estimates a bioaccumulation factor of greater than or equal to 1,000. The Order was issued under TSCA section 5(a)(3)(B)(ii)(I) based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substances may present an unreasonable risk of injury to the environment. The Order was also issued under TSCA sections 5(a)(3)(B)(ii)(II) and 5(e)(1)(A)(ii)(II), based on a finding that the substances are or will be produced in substantial quantities and that the substances either enter or may reasonably be anticipated to enter the environment in substantial quantities, or there is or may be significant (or substantial) human exposure to the substances.

To protect against these risks, the Order requires:

1. Submission to EPA of certain testing before exceeding the three-year time limit specified in the Order; and

2. Use of the PMN substances only for the confidential uses specified in the Order.

The proposed SNUR would designate as a “significant new use” the absence of these protective measures.

*Potentially useful information:* EPA has determined that certain information about the fate and environmental effects of the PMN substances may be potentially useful to characterize the effects of the PMN substances in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. The submitter has agreed not to manufacture the PMN substances beyond three years without performing a specific biodegradation study and an ecotoxicity testing scheme for P-15-353 to determine the rate of loss of the parent PMN substances and formation and identification of degradation products, and to assess their toxicity.

*CFR citation:* 40 CFR 721.11221 (P-15-353) and 40 CFR 721.11222 (P-15-433)

**PMN Number:** P-16-186.

*Chemical Name:* Sodium branched chain alkyl hydroxyl and branched chain alkenyl sulfonates (generic).

*CAS Number:* Not available.

*Effective date of TSCA section 5(e) Order:* June 26, 2018.

*Basis for TSCA section 5(e) Order:* The PMN states that the generic (non-confidential) use of the substance will be as a surfactant. EPA identified concern for lung effects based on surfactant activity if respirable particles are inhaled and concern for irritation based on potential surfactant activity to all exposed tissues. EPA also identified concern for developmental toxicity based on

data provided for an analogue. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I) of TSCA, based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health and the environment. To protect against these risks, the Order requires:

1. Use of personal protective equipment to prevent dermal exposure where there is a potential for dermal exposure;
2. Refraining from modifying the manufacture, processing or use of the PMN substance in a manner that results in inhalation exposure to vapor, dust, spray, mist or aerosol;
3. Use of the PMN substance only for the confidential use specified in the Order; and
4. Establishment and use of a hazard communication program, including human health precautionary statements on each label and Safety Data Sheet (SDS).

The proposed SNUR would designate as a “significant new use” the absence of these protective measures.

*Potentially useful information:* EPA has determined that certain information about the health effects of the PMN substance may be potentially useful to characterize the effects of the PMN substance in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has also determined that the results of specific pulmonary toxicity testing would help characterize the potential health effects of the PMN substance. Although the Order does not require this test, the Order’s restrictions on manufacture, processing, distribution in commerce, and use of the PMN substance will remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

*CFR citation:* 40 CFR 721.11223.

**PMN Number:** P-16-207.

*Chemical Name:* Spiro tetrafluoroborate (generic).

*CAS Number:* Not available.

*Effective date of TSCA section 5(e) Order:* August 6, 2018.

*Basis for TSCA section 5(e) Order:* The PMN states that the use of the substance will be as an additive for an electrolyte solution. Based on physical/chemical properties and analysis of test data on the PMN substance, EPA has identified concern for developmental neurotoxicity, effects to the bladder, liver, kidney, thymus, stomach, thyroid, and blood. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(I)(A)(ii)(I) based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substances may present an unreasonable risk of injury to human health or the environment. To protect against these risks, the Order requires:

1. Submission to EPA of certain toxicity testing before exceeding the aggregate volumes specified in the Order;
2. Use of personal protective equipment where there is potential for dermal exposure;
3. Use of a National Institute of Occupational Safety and Health (NIOSH)-certified respirator with an assigned protection factor (APF) of at least 1000 (where there is potential for inhalation exposure) or compliance with a NCEL of 0.2 mg/m<sup>3</sup> as an 8-hour time-weighted average;
4. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS;
5. Refraining from domestic manufacture in the United States (i.e., import only); and

6. Use of the PMN substance only for the confidential use specified in the Order.

The proposed SNUR would designate as a “significant new use” the absence of these protective measures.

*Potentially useful information:* EPA has determined that certain information about environmental and health effects of the PMN substance may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this SNUR. The submitter has agreed not to exceed a certain production volume limit without performing specific reproductive toxicity testing and acute aquatic toxicity testing.

*CFR citation:* 40 CFR 721.11224.

**PMN Numbers:** P-16-246 and P-16-516.

*Chemical Names:* 2-pyridinecarboxylic acid, 6-(4-chloro-2-fluoro-3-methoxyphenyl)-4,5-difluoro-, phenylmethyl ester (P-16-246) and 2-pyridinecarboxylic acid, 4-amino-6-(4-chloro-2-fluoro-3-methoxyphenyl)-5-fluoro-, phenylmethyl ester, hydrochloride (1:1) (P-16-516).

*CAS Numbers:* 1391033-38-7 (P-16-246) and not available (P-16-516).

*Effective date of TSCA section 5(e) Order:* May 21, 2017.

*Basis for TSCA section 5(e) Order:* The PMNs state that the generic (non-confidential) use of the substances will be as chemical intermediates. Based on analysis of test data on analogous esters, EPA has identified concerns for carcinogenicity, developmental/reproductive effects, systemic toxicity, sensitization, and aquatic/terrestrial toxicity. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substances may present an

unreasonable risk of injury human health and the environment. To protect against these risks, the Order requires:

1. Submission of certain toxicity testing on the PMN substances prior to exceeding the time limits specified in the Order;
2. Use of personal protective equipment where there is a potential for dermal exposure;
3. Use of a NIOSH-certified respirator with an APF of at least 50 where there is a potential for inhalation exposure;
4. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS;
5. Use of the PMN substances only for the confidential uses specified in the Order; and
6. No release of the PMN substances to surface waters.

The proposed SNUR would designate as a “significant new use” the absence of these protective measures.

*Potentially useful information:* EPA has determined that certain information about the health effects of the PMN substances may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. The submitter has agreed not to exceed certain time limits without performing sensitization, mutagenicity, reproductive/developmental, and carcinogenicity effects testing. EPA has also determined that the results of acute aquatic toxicity testing would help characterize the potential environmental effects of the PMN substances. Although the Order does not require these tests, the Order’s restrictions on manufacture, processing, distribution in commerce, and disposal will remain in effect until the Order is modified or revoked by EPA based on submission of this or

relevant information.

*CFR citations:* 40 CFR 721.11225 (P-16-246) and 40 CFR 721.11226 (P-16-516).

**PMN Numbers:** P-16-271 and P-16-450.

*Chemical Name:* 1,2,4-Benzenetricarboxylic acid, 1,2,4-trinonyl ester.

*CAS Number:* 1817723-10-6.

*Effective date of TSCA section 5(e) Orders:* June 22, 2018.

*Basis for TSCA section 5(e) Orders:* The PMNs state that the use of the substance will be used as a plasticizer for wire and cable insulation. EPA identified concerns for the PMN substance as a mild skin irritant as well as for blood, developmental, systemic, maternal, and male reproductive toxicity based on analysis of test data on analogous trimellitate esters. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I) of TSCA, based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health and the environment. The Order was also issued under TSCA sections 5(a)(3)(B)(ii)(II) and 5(e)(1)(A)(ii)(II), based on a finding that the substance is or will be produced in substantial quantities and that the substance either enters or may reasonably be anticipated to enter the environment in substantial quantities, or there is or may be significant (or substantial) human exposure to the substance. To protect against these risks, the Orders require:

1. Submit to EPA certain toxicity testing before manufacturing (including import) a total of 1,750,000 kilograms (in each Order) of the PMN substance;
2. Submit to EPA additional toxicity testing which will be determined upon EPA review of the initial toxicity testing results;

3. Use of personal protective equipment to prevent dermal exposure where there is a potential for dermal exposure;
4. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS and worker training in accordance with the Hazard Communication section of the Orders;
5. Refraining from domestic manufacture in the United States (i.e., import only); and
6. Use of the PMN substance only as plasticizer for wire and cable insulation.

The proposed SNUR would designate as a “significant new use” the absence of these protective measures.

*Potentially useful information:* EPA has determined that certain information about the health and environmental effects of the PMN substance may be potentially useful in support of a request by the PMN submitters to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. The submitters have agreed not to exceed certain production volume limits without performing reproductive/developmental toxicity tests and aquatic sediment toxicity tests.

*CFR citation:* 40 CFR 721.11227.

**PMN Number:** P-16-388.

*Chemical Name:* Aliphatic polyamines, polymers with bisphenol A and epichlorohydrin (generic).

*CAS Number:* Not available.

*Effective date of TSCA section 5(e) Order:* July 23, 2018.

*Basis for TSCA section 5(e) Order:* The PMN states that the generic (non-confidential) use of the substance will be as a hardener for epoxy coating. Based on the high percentage of amines and a



high pH when in liquid formulation, EPA has identified concern for irritation to the eyes, skin, mucous membranes, and lungs. The Order was issued under TSCA sections 5(a)(3)(B)(i) and 5(e)(1)(A)(i), based on a finding that the available information is insufficient to permit a reasoned evaluation of the human health effects of the PMN substances. To protect against these risks, the Order requires:

1. Use of the PMN substance only for the confidential use specified in the Order;
2. Use of personal protective equipment to prevent dermal exposure where there is potential for dermal exposure;
3. No use of the PMN substance in a consumer product; and
4. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS.

The proposed SNUR would designate as a “significant new use” the absence of these protective measures.

*Potentially useful information:* EPA has determined that certain information about the health effects of the PMN substance may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has also determined that the results of skin irritation and skin sensitization toxicity testing would help characterize the potential health effects of the PMN substance. Although the Order does not require these tests, the Order’s restrictions on manufacture, distribution in commerce, and use of the PMN substance will remain in effect until the Order is modified or revoked by EPA based on submission of this or relevant information.

*CFR citation:* 40 CFR 721.11228.

**PMN Numbers:** P-16-489, P-16-490, and P-16-491.

*Chemical Name:* Epoxy-amine adduct, methanesulfonates (generic).

*CAS Number:* Not available.

*Effective date of TSCA section 5(e) Order:* June 11, 2018.

*Basis for TSCA section 5(e) Order:* The PMNs state that the generic (non-confidential) use of the substances will be open, non-dispersive. Based on physical/chemical properties of the PMN substances, EPA has identified concern for lung toxicity. Ecotoxicity hazards were identified based on structural analysis relationship ("SAR") predictions for polycationic polymers. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substances may present an unreasonable risk of injury to human health and the environment. To protect against these risks, the Order requires:

1. Refrain from manufacture, processing, or use of the PMN substances that result in inhalation exposure to vapor, mist, or aerosols;
2. Refrain from manufacture, processing, or use of the PMN substances for consumer use;
3. No release of the PMN substances from manufacturing, processing, or use resulting in surface water concentrations that exceed 208 parts per billion (ppb); and
4. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS.

The proposed SNUR would designate as a "significant new use" the absence of these protective measures.

*Potentially useful information:* EPA has determined that certain information about the

physical/chemical properties, environmental and health effects of the PMN substances may be potentially useful to characterize the effects of the PMN substances in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has also determined that the results of certain physical/chemical properties, acute aquatic toxicity testing, and pulmonary effects testing would help characterize the potential health effects of the PMN substances. Although the Order does not require these tests, the Order's restrictions on manufacture, distribution in commerce, and use of these PMN substances will remain in effect until the Order is modified or revoked by EPA based on submission of this or relevant information.

*CFR citation:* 40 CFR 721.11229.

**PMN Number:** P-16-509.

*Chemical Name:* Modified ethylene-vinyl alcohol copolymer (generic).

*CAS Number:* Not available.

*Effective date of TSCA section 5(e) Order:* July 23, 2018.

*Basis for TSCA section 5(e) Order:* The PMN states that the generic (non-confidential) use of the PMN substance will be for packaging applications. EPA identified concerns for lung effects if respirable particles are inhaled based on physical/chemical properties. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health and the environment. To protect against these risks, the Order requires refraining from manufacturing (which includes import), processing or using the PMN substance with particle size less than 50 microns.

The proposed SNUR would designate as a “significant new use” the absence of this protective measure.

*Potentially useful information:* EPA has determined that certain information about health effects of the PMN substance may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has also determined that the results of specific pulmonary toxicity testing would help characterize the potential health effects of the PMN substance. Although the Order does not require these tests, the Order’s restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

*CFR citation:* 40 CFR 721.11230.

**PMN Number:** P-16-546.

*Chemical Name:* Cashew, nutshell liq., polymer with acid and halohydrin (generic).

*CAS Number:* Not available.

*Effective date of TSCA section 5(e) Order:* July 20, 2018.

*Basis for TSCA section 5(e) Order:* The PMN states that the use of the substance will be as an adhesion application. Based on the presence of cashew, nutshell liquid in the PMN substance, EPA has identified concerns for sensitization from dermal exposure. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substances may present an unreasonable risk of injury to human health and the environment. To protect against these risks, the Order requires:

1. Use of personal protective equipment including chemically impervious gloves and eye goggles where there is a potential for dermal exposure;
2. Use of a NIOSH-certified respirator with an APF of at least 50 to mitigate inhalation exposure and 1000 where the PMN substance has a use involving an application that generates vapor, mist, dust or aerosol;
3. No use of the PMN substance use in a consumer product; and
4. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS.

The proposed SNUR would designate as a “significant new use” the absence of these protective measures.

*Potentially useful information:* EPA has determined that certain information about the health effects of the PMN substance may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has also determined that the results of sensitization testing would help characterize the potential health effects of the PMN substance. Although the Order does not require these tests, the Order’s restrictions on manufacture, distribution in commerce, and use of the PMN substance will remain in effect until the Order is modified or revoked by EPA based on submission of this or relevant information.

*CFR citation:* 40 CFR 721.11231.

**PMN Number:** P-16-589.

*Chemical Name:* Pentaerythritol ester of mixed linear and branched carboxylic acids (generic).

*CAS Number:* Not available.

*Effective date of TSCA section 5(e) Order:* October 4, 2018.

*Basis for TSCA section 5(e) Order:* The PMN states that the generic (non-confidential) use of the substance will be as a synthetic aircraft engine lubricant for contained use industrial lubricant. EPA identified concern for developmental, kidney, liver, and specific organ effects based on test data on the potential branch acid moiety hydrolysis product of the PMN substance. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I) of TSCA, based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to health and the environment. To protect against these risks, the Order requires:

1. Use of personal protective equipment to prevent dermal exposure where there is a potential for dermal exposure;
2. Refraining from modifying the manufacture or processing of the PMN substance in a manner that results in inhalation exposure to the substance;
3. Use of the PMN substance only for the confidential use specified in the Order;
4. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS; and
5. No release of the PMN substance resulting in exceedance of a surface water concentration of 330 ppb.

The proposed SNUR would designate as a “significant new use” the absence of these protective measures.

*Potentially useful information.* EPA has determined that certain information about the environmental fate and health effects of the PMN substance would be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor

is considering submitting a SNUN for a significant new use that would be designated by this SNUR. EPA has also determined that the results of hydrolysis testing and reproductive/developmental toxicity testing would help characterize the potential health effects of the PMN substance. Although the Order does not require this test, the Order's restrictions on manufacture, processing, distribution in commerce, and use of the PMN substance will remain in effect until the Order is modified or revoked by EPA based on submission of this or relevant information.

*CFR citation:* 40 CFR 721.11232.

**PMN number:** P-17-116.

*Chemical Name:* Cashew nut shell liquid, branched polyester-polyether polyol (generic).

*CAS Number:* Not available.

*Effective date of TSCA section 5(e) Order:* September 6, 2017.

*Basis for TSCA section 5(e) Order:* The PMN states that the use of the PMN substance will be as a polyurethane foam to raise concrete slabs. Based on the presence of cashew nut shell liquid, there is concern for sensitization. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health.

To protect against this risk, the Order requires:

1. Submit to EPA certain toxicity testing before manufacturing (including import) a total of 65,000 kilograms of the PMN substance;
2. Provide personal protective equipment to its workers to prevent dermal exposure, including impervious gloves where there is potential for dermal exposure;
3. Refraining from domestic manufacture in the United States (i.e., import only);

4. Manufacture (including import) the PMN substance with no greater than 0.1% weight cashew nut oil;

5. Not use the PMN substance involving an application method that results in the generation of vapor, mist, or aerosol; and

6. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS.

The proposed SNUR would designate as a “significant new use” the absence of these protective measures.

*Potentially useful information:* EPA has determined that certain information about the health effects of the PMN substance may be potentially useful in support of a request by the PMN submitters to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. The submitter has agreed not to exceed certain production volume limit without performing sensitization testing.

*CFR citation:* 40 CFR 721.11233.

**PMN Number:** P-17-121.

*Chemical Name:* Methylene diphenyl diisocyanate terminated polyurethane resin (generic).

*CAS Number:* Not available.

*Effective date of TSCA section 5(e) Order:* July 17, 2018.

*Basis for TSCA section 5(e) Order:* The PMN states that the use of the substance will be as a polyurethane used in an adhesive. Based on the isocyanate moiety, EPA has identified concerns for respiratory and dermal sensitization and lung and mucous membrane irritation. The Order was issued under TSCA section 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I) based on a finding that in



the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health and the environment. The Order was also issued under TSCA sections 5(a)(3)(B)(ii)(II) and 5(e)(1)(A)(ii)(II), based on a finding that the substance that the substance is or will be produced in substantial quantities and that the substance either enters or may reasonably be anticipated to enter the environment in substantial quantities, or there is or may be significant (or substantial) human exposure to the substance.

To protect against these risks, the Order requires:

1. Submitting to EPA the results of annual medical surveillance monitoring;
2. Use of personal protective equipment to prevent dermal exposure where there is potential for dermal exposure;
3. Use of NIOSH-certified respirators with an APF of at least 50 where there is potential for inhalation exposure;
4. No application methods of the PMN substance that generate a vapor, mist, aerosol, spray, or dust;
5. Refrain from manufacturing, processing, or using the PMN substance for consumer use or for commercial uses that could introduce the substance into a consumer setting; and
6. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS.

The proposed SNUR would designate as a “significant new use” the absence of these protective measures.

*Potentially useful information:* EPA has determined that certain information about the health effects of the PMN substance may be potentially useful in support of a request by the PMN submitters to modify the Order, or if a manufacturer or processor

is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. The submitter has agreed to perform annual medical surveillance monitoring as specified in the Order.

*CFR citation:* 40 CFR 721.11234.

**PMN Number:** P-17-328.

*Chemical Name:* 2-Furancarboxylic acid, tetrahydro-.

*CAS Number:* 16874-33-2.

*Effective date of TSCA section 5(e) Order:* July 26, 2018.

*Basis for TSCA section 5(e) Order:* The PMN states that the use of the substance will be as a selective polishing agent for chemical mechanical planarization slurry for semiconductor wafer processing. Based on analysis of test data on an analogous chemical, EPA has identified concern for severe eye irritation, blood effects, reproductive effects, and immunotoxicity. Based on physical/chemical properties the substance is also expected to be corrosive, cause skin and eye burns, systemic effects, respiratory and digestive tract irritation with possible burns, pulmonary edema, solvent neurotoxicity, and solvent irritation. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health or the environment. To protect against these risks, the Order requires:

1. Use of personal protective equipment involving impervious gloves and chemical safety goggles where there is potential for dermal exposure;
2. Use of a NIOSH-certified respirator with an APF of at least 50 where there is a potential for inhalation exposure;
3. Refraining from domestic manufacture in the United States (i.e., import only); and

4. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS.

The proposed SNUR would designate as a “significant new use” the absence of these protective measures.

*Potentially useful information:* EPA has determined that certain information about the health effects of the PMN substance may be potentially useful to characterize the effects of the PMN substance in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has also determined that the results of reproductive/developmental toxicity testing would help characterize the potential health effects of the PMN substance. Although the Order does not require these tests, the Order’s restrictions on manufacture, processing, distribution in commerce, and use of the PMN substance will remain in effect until the Order is modified or revoked by EPA based on submission of this or relevant information.

*CFR citation:* 40 CFR 721.11235.

**PMN Numbers:** P-17-373 and P-17-374.

*Chemical Names:* Substituted heteromonocycle, homopolymer, alkyl substituted carbamate, substituted alkyl ester, substituted heteromonocycle, homopolymer, alkyl substituted carbamate, substituted alkyl ester (generic) (P-17-373) and polysiloxanes, di alkyl, substituted alkyl group terminated, alkoxyated, reaction products with alkanolic acid, isocyanate substituted-alkyl carbomonocycle and polyol (generic) (P-17-374).

*CAS Numbers:* Not available.

*Effective date of TSCA section 5(e) Order:* June 7, 2018.

*Basis for TSCA section 5(e) Order:* The PMNs state that the use of P-17-373 will be as an ultraviolet curable resin-overprint varnish and P-17-374 will be as an ultraviolet curable resin. Based on test data for structurally similar acrylates, EPA has identified concerns for eye and skin irritation, sensitization, mutagenicity, oncogenicity, liver and kidney toxicities. EPA also identified concern for developmental toxicity based on analogy to triethanolamines. Based on analogy to acrylates and carbamate esters, P-17-374 could cause environmental effects at concentrations of 110 ppb. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substances may present an unreasonable risk of injury to health and the environment. To protect against these risks, the Order requires:

1. Use of personal protective equipment to prevent dermal exposure where there is potential for dermal exposure;
2. Use of NIOSH-certified respirators with an APF of at least 50 where there is potential for inhalation exposure;
3. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS;
4. Refraining from domestic manufacture in the United States (i.e., import only);
5. Import of P-17-374 with no more than 0.1% residual isocyanate;
6. Import of the PMN substances to have a number average molecular weight of greater than or equal to 1000 daltons;
7. Refraining from using the PMN substances other than as an ultraviolet curable resin for coatings; and
8. No release of P-17-374 resulting in surface water concentrations that exceed 110 ppb.

The proposed SNUR would designate as a “significant new use” the absence of these protective measures.

*Potentially useful information:* EPA has determined that certain information about the health effects of the PMN substances may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has also determined that the results of sensitization testing would help characterize the potential health effects of the PMN substances. Although the Order does not require this test, the Order’s restrictions on manufacture, processing, distribution in commerce, and use of the PMN substances will remain in effect until the Order is modified or revoked by EPA based on submission of this or relevant information.

*CFR citation:* 40 CFR 721.11236

(P-17-373) and 40 CFR 721.11239 (P-17-374).

**PMN Number:** P-18-17.

*Chemical Name:* Substituted carbomonocycle, polymer with substituted heteromonocycle and substituted polyalkylene glycol (generic).

*CAS Number:* Not available.

*Effective date of TSCA section 5(e) Order:* June 21, 2018.

*Basis for TSCA section 5(e) Order:* The PMN states that the use of the substance will be for corrosion protection. Based on the physical/chemical properties of the PMN substance, analysis of test data, and structurally analogous epoxides, EPA identified concerns for mutagenicity, oncogenicity, developmental toxicity, male reproductive effects, liver and kidney toxicity, and dermal and respiratory sensitization. The Order was issued under TSCA section 5(a)(3)(B)(ii)(I),

based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to health and the environment. To protect against these risks, the Order requires:

1. Refraining from domestic manufacture in the United States (i.e., import only);
2. Refrain from using the PMN substance other than for primer coating for corrosion protection;
3. Import the PMN substance with an average molecular weight greater than 1000 daltons with no more than 10% less than 500 daltons and no more than 25% less than 1000 daltons;
4. Use of personal protective equipment to prevent dermal exposure where there is potential for dermal exposure;
5. Use of NIOSH-certified respirators with an APF of at least 1000 where there is potential for inhalation exposure; and
6. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS.

The proposed SNUR would designate as a “significant new use” the absence of these protective measures.

*Potentially useful information:* EPA has determined that certain information about the environmental and health effects of the PMN substance may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has also determined that the results of water solubility, acute and chronic aquatic toxicity, systemic toxicity, sensitization, and carcinogenicity testing would help

characterize the potential health and environmental effects of the PMN substance. Although the Order does not require this information, the Order's restrictions on manufacture, processing, distribution in commerce, and use of the PMN substance will remain in effect until the Order is modified or revoked by EPA based on submission of this or relevant information.

*CFR citation:* 40 CFR 721.11240.

**PMN Number:** P-18-40.

*Chemical Name:* Alkanedioic acid, polymers with alkanolic acid-dipentaerythritol reaction products, substituted alkanedioic acid, substituted alkanolic acid, isocyanato-(isocyanatoalkyl)-alkyl substituted carbomonocycle and alkyl substituted alkanediol (generic).

*CAS Number:* Not available.

*Effective date of TSCA section 5(e) Order:* July 26, 2018.

*Basis for TSCA section 5(e) Order:* The PMN states that the use of the substance will be as a binder for ultraviolet curable coating resin. Based on physical/chemical properties, data on the PMN substance, and analysis of test data on an analogous chemical, EPA has identified concerns for developmental toxicity, oncogenicity, liver and kidney toxicity, ocular irritation, sensitization, irritation/corrosion, and eye damage. The Order was issued under TSCA section 5(a)(3)(B)(ii)(I) based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to health or the environment. To protect against these risks, the Order requires:

1. Refraining from domestic manufacture in the United States (i.e., import only);
2. Only use the PMN substance as a binder for ultraviolet curable coating resins;
3. Import the PMN substance with a number average molecular weight of greater than 1000 daltons;

4. Import the PMN substance with no greater than 20% of the acid moiety;
5. Use of personal protective equipment where there is potential for dermal exposure;
6. Use of a NIOSH-certified respirator with an APF of at least 1000 where there is a potential for inhalation exposure; and
7. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS.

The proposed SNUR would designate as a “significant new use” the absence of these protective measures.

*Potentially useful information:* EPA has determined that certain information about the health and environmental effects of the PMN substance may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has also determined that the results of water solubility, acute and chronic aquatic toxicity, systemic toxicity, sensitization, and carcinogenicity testing would help characterize the potential health and environmental effects of the PMN substance. Although the Order does not require these tests, the Order’s restrictions on manufacture, processing, distribution in commerce, and use of the PMN substance will remain in effect until the Order is modified or revoked by EPA based on submission of this or relevant information.

*CFR citation:* 40 CFR 721.11241.

**PMN Number:** P-18-46.

*Chemical Name:* Substituted carbomonocycle, polymer with diisocyanatoalkane, substituted alkylacrylate blocked (generic).

*CAS Number:* Not available.



*Effective date of TSCA section 5(e) Order:* June 21, 2018.

*Basis for TSCA section 5(e) Order:* The PMN states that the use of the substance will be as an ultraviolet curable resin. Based on physical/chemical properties, analysis of test data on the PMN substance, and structurally analogous acrylates, EPA has identified concerns for mutagenicity, oncogenicity, developmental toxicity, liver and kidney toxicity, dermal and respiratory sensitization. The Order was issued under TSCA section 5(a)(3)(B)(ii)(I) based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to health and the environment. To protect against these risks, the Order requires

1. Refraining from domestic manufacture in the United States (i.e., import only);
2. Refrain from using the PMN substance other than as an ultraviolet curable resin;
3. Import the PMN substance with an average molecular weight greater than 1390 daltons with no more than 11% less than 500 daltons and no more than 30% less than 1000 daltons;
4. Use of personal protective equipment to prevent dermal exposure where there is potential for dermal exposure;
5. Use of NIOSH-certified respirators with an APF of at least 1000 where there is potential for inhalation exposure; and
6. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS.

The proposed SNUR would designate as a “significant new use” the absence of these protective measures.

*Potentially useful information:* EPA has determined that certain information about the health and

environmental effects of the PMN substance may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has also determined that the results of water solubility, acute and chronic aquatic toxicity, pulmonary toxicity, and sensitization, testing would help characterize the potential health and environmental effects of the PMN substance. Although the Order does not require these tests, the Order's restrictions on manufacture, processing, distribution in commerce, and use of the PMN substance will remain in effect until the Order is modified or revoked by EPA based on submission of this or relevant information.

*CFR citation:* 40 CFR 721.11242.

**PMN Number:** P-18-47.

*Chemical Name:* 1,2-Ethanedio1, 1,2-dibenzoate.

*CAS Number:* 94-49-5.

*Effective date of TSCA section 5(e) Order:* July 31, 2018.

*Basis for TSCA section 5(e) Order:* The PMN states that the use of the substance will be as a phlegmatizer (stabilizer for compounds susceptible to detonation) for peroxides for use with polyester and vinyl ester resins as well as with curable unsaturated polyester and methacrylic resins. Based on test data on the PMN substance, and analysis of test data on analogous chemicals, EPA has identified concerns for blood, liver, and kidney toxicity, neurotoxicity, immunotoxicity, and reproductive and developmental toxicity, and ecotoxicity. The Order was issued under TSCA sections 5(a)(3)(B)(i) and 5(e)(1)(A)(i), based on a finding that the available information is insufficient to permit a reasoned evaluation of the health effects of the PMN substance. The Order was also issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I),

based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to health and the environment.

Additionally, the Order was issued under 5(a)(3)(B)(ii)(II) and 5(e)(1)(A)(ii)(II), based on a finding that the substance is or will be produced in substantial quantities and that the substance either enters or may reasonably be anticipated to enter the environment in substantial quantities, or there is or may be significant (or substantial) human exposure to the substance. To protect against these risks, the Order requires:

1. Use of personal protective equipment where there is potential for dermal exposure;
2. Use of a NIOSH-certified respirator with an APF of at least 25 where there is a potential for inhalation exposure;
3. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS;
4. Refraining from domestic manufacture in the United States (i.e., import only);
5. Only use the PMN substance as a phlegmatizer (stabilizer for compounds susceptible to detonation) for peroxides for use with polyester and vinyl ester resins as well as with curable unsaturated polyester and methacrylic resins; and
6. No release of the PMN substance resulting in surface water concentrations that exceed 10 ppb.

The proposed SNUR would designate as a “significant new use” the absence of these protective measures.

*Potentially useful information:* EPA has determined that certain information about the health and environmental effects of the PMN substance may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is

considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has also determined that the results of acute aquatic toxicity and neurotoxicity/developmental neurotoxicity/prenatal development testing would help characterize the potential health and environmental effects of the PMN substance. Although the Order does not require these tests, the Order's restrictions on manufacture, processing, distribution in commerce, and use of the PMN substance will remain in effect until the Order is modified or revoked by EPA based on submission of this or relevant information.

*CFR citation:* 40 CFR 721.11243.

**PMN Number:** P-18-51.

*Chemical Name:* Alkenoic acid, reaction products with polymers with isocyanatoalkane and substituted alkenoic acid, substituted monoacrylate alkenoate-blocked (generic).

*CAS Number:* Not available.

*Effective date of TSCA section 5(e) Order:* July 30, 2018.

*Basis for TSCA section 5(e) Order:* The PMN states that the use of the substance will be as a waterborne ultraviolet curable coating resin binder for inkjet, ink, or overprint varnish. Based on physical/chemical properties, available data on the PMN substance and comparison to structurally analogous acrylates, EPA has identified concern for developmental toxicity, sensitization, irritation, corrosion, and eye damage. The Order was issued under TSCA section 5(a)(3)(B)(ii)(I) based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substances may present an unreasonable risk of injury to human health or the environment. To protect against these risks, the Order requires:

1. Refraining from domestic manufacture in the United States (i.e., import only);

2. Only use the PMN substance as a waterborne ultraviolet curable coating resin binder for inkjet, ink, or overprint varnish;
3. Import the PMN substance with no greater than 24% branched alkyl acid moiety content;
4. Import the PMN substance with no greater than 0.1% isocyanate content;
5. Use of personal protective equipment where there is potential for dermal exposure;
6. Use of a NIOSH-certified respirator with an APF of at least 1000 where there is a potential for inhalation exposure;
7. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS; and
8. No release of the PMN substance resulting in surface water concentrations that exceed 660 ppb.

The proposed SNUR would designate as a “significant new use” the absence of these protective measures.

*Potentially useful information:* EPA has determined that certain information about the health and environmental effects of the PMN substance may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has also determined that the results of water solubility, acute and chronic aquatic toxicity, developmental toxicity, and sensitization testing would help characterize the potential health and environmental effects of the PMN substance. Although the Order does not require these tests, the Order’s restrictions on manufacture, processing, distribution in commerce, and use of the PMN substance will remain in effect until the Order is modified or revoked by

EPA based on submission of this or relevant information.

*CFR citation:* 40 CFR 721.11244.

**PMN Numbers:** P-18-71 and P-18-79.

*Chemical Names:* Aromatic dicarboxylic acid, compd. with alkane diamines, polymer with alkane diamine and alkane dicarboxylic acid (generic) (P-18-71) and Aromatic dicarboxylic acid, compd. with alkyl diamines, homopolymer (generic) (P-18-79).

*CAS Numbers:* Not available.

*Effective date of TSCA section 5(e) Order:* July 6, 2018.

*Basis for TSCA section 5(e) Order:* The PMNs state that the generic (non-confidential) use of the substances will be as engineering thermoplastic. EPA identified concern for lung effects if the PMN substances are made with a particle size less than 10 microns based on analogy to similar poorly soluble particles. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I) of TSCA, based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substances may present an unreasonable risk of injury to human health and the environment. To protect against this risk, the Order requires manufacture of the PMN substances with a particle size greater than 10 microns. The proposed SNUR would designate as a “significant new use” the absence of this protective measure.

*Potentially useful information:* EPA has determined that certain information about the health effects of the PMN substances would be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has also determined that the results of pulmonary effects testing would help characterize the potential health effects of the PMN substance. Although the Order does not require this test, the Order’s

restrictions on manufacture, processing, distribution in commerce, and use of the PMN substances will remain in effect until the Order is modified or revoked by EPA based on submission of this or relevant information.

*CFR citations:* 40 CFR 721.11245 (P-18-71) and 40 CFR 721.11246 (P-18-79).

**PMN Number:** P-18-82.

*Chemical Name:* Aspartic acid, tallow modified diester (generic).

*CAS Number:* Not available.

*Effective date of TSCA section 5(e) Order:* July 3, 2018.

*Basis for TSCA section 5(e) order:* The PMN states that the use of the substance will be as an intermediate used in the manufacture of a surface-active agent. Based on test data available for an analogue, EPA has identified concerns for irritation, blood effects, neurotoxicity and surfactant effects in the lungs based on analogue data. Based on SAR analysis of anionic surfactants, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substances may present an unreasonable risk of injury to human health and the environment. To protect against these risks, the Order requires:

1. Manufacture, process and use of the PMN substance only as stated in the PMN submission;
2. Use only as an intermediate;
3. Refraining from modifying the manufacture, processing or use in a manner resulting in inhalation exposure;

4. Use of personal protective equipment to prevent dermal exposure (where there is potential for dermal exposure);
5. Establishment and use of a hazard communication program, including human health precautionary statement on each label and in the SDS;
6. That PMN residuals will be recycled back into the process as stated in the PMN; and
7. No release of the PMN substance resulting in surface water concentrations that exceed 1 ppb.

The proposed SNUR would designate as a “significant new use” the absence of these protective measures.

*Potentially useful information:* EPA has determined that certain information about the environmental and health effects of the PMN substance may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has also determined that the results of acute aquatic toxicity, pulmonary effects, and specific target organ toxicity testing would help characterize the potential environmental and health effects of the PMN substance. Although the Order does not require these tests, the Order’s restrictions on manufacture, processing, distribution in commerce, use, and disposal of the PMN substance will remain in effect until the Order is modified or revoked by EPA based on submission of this or relevant information.

*CFR citation:* 40 CFR 721.11247.

**PMN Number:** P-18-130.

*Chemical Name:* Substituted alkanediol, polymer with heteromonocycles, alkenoate, metal complexes (generic).



*CAS Number:* Not available.

*Effective date of TSCA section 5(e) Order:* July 26, 2018.

*Basis for TSCA section 5(e) Order:* The PMN states that the use of the substance will be as an adhesion promoter for industrial application. Based on analysis of analogous acrylates, and physical/chemical properties, EPA has identified concerns for mutagenicity, oncogenicity, developmental toxicity, sensitization, irritation, and liver and kidney toxicity. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to health and the environment. To protect against these risks, the Order requires:

1. Use of personal protective equipment where there is a potential for dermal exposure;
  2. Use of a NIOSH-certified respirator with an APF of at least 50 to mitigate inhalation and 1000 where the PMN substance has a use involving spray application;
  3. Refraining from domestic manufacture in the United States (i.e., import only);
  4. Use of the PMN substance only as an adhesion promoter for industrial applications;
- and
5. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS.

The proposed SNUR would designate as a “significant new use” the absence of these protective measures.

*Potentially useful information:* EPA has determined that certain information about the health effects of the PMN substance may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a

SNUN for a significant new use that would be designated by this proposed SNUR. EPA has also determined that the results of absorption, distribution, metabolism, elimination, genotoxicity, and sensitization testing would help characterize the potential health effects of the PMN substance. Although the Order does not require these tests, the Order's restrictions on manufacture, distribution in commerce, and use of the PMN substance will remain in effect until the Order is modified or revoked by EPA based on submission of this or relevant information.

*CFR citation:* 40 CFR 721.11248.

## **V. Rationale and Objectives of the Proposed Rule**

### *A. Rationale*

During review of the PMNs submitted for the chemical substances that are subject to these proposed SNURs, EPA concluded that for all 28 chemical substances regulation was warranted under TSCA section 5(e), pending the development of information sufficient to make reasoned evaluations of the health or environmental effects of the chemical substances. The basis for such findings is outlined in Unit IV. Based on these findings, TSCA section 5(e) Orders requiring the use of appropriate exposure controls were negotiated with the PMN submitters. The SNURs would identify as significant new uses any manufacturing, processing, use, distribution in commerce, or disposal that does not conform to the restrictions imposed by the underlying Orders, consistent with TSCA section 5(f)(4).

### *B. Objectives*

EPA is proposing these SNURs for specific chemical substances which have undergone premanufacture review because the Agency wants to achieve the following objectives about the significant new uses designated in this rule:

- EPA would receive notice of any person's intent to manufacture or process a listed

chemical substance for the described significant new use before that activity begins.

- EPA would have an opportunity to review and evaluate data submitted in a SNUN before the notice submitter begins manufacturing or processing a listed chemical substance for the described significant new use.

- EPA would be able to either determine that the prospective manufacture or processing is not likely to present an unreasonable risk, or to take necessary regulatory action associated with any other determination, before the described significant new use of the chemical substance occurs.

- EPA would identify as significant new uses any manufacturing, processing, use, distribution in commerce, or disposal that does not conform to the restrictions imposed by the underlying Orders, consistent with TSCA section 5(f)(4).

Issuance of a SNUR for a chemical substance does not signify that the chemical substance is listed on the TSCA Chemical Substance Inventory (TSCA Inventory). Guidance on how to determine if a chemical substance is on the TSCA Inventory is available on the Internet at <http://www.epa.gov/opptintr/existingchemicals/pubs/tscainventory/index.html>.

## **VI. Applicability of the Proposed Significant New Use Designation**

To establish a significant new use, EPA must determine that the use is not ongoing. The chemical substances subject to this proposed rule have undergone premanufacture review. In cases where EPA has not received a notice of commencement (NOC) and the chemical substance has not been added to the TSCA Inventory, no person may commence such activities without first submitting a PMN. Therefore, for chemical substances for which an NOC has not been submitted EPA concludes that the designated significant new uses are not ongoing.

When chemical substances identified in this proposed rule are added to the TSCA

Inventory, EPA recognizes that, before the rule is effective, other persons might engage in a use that has been identified as a significant new use. However, TSCA section 5(e) Orders have been issued for all of the chemical substances, and the PMN submitters are prohibited by the TSCA section 5(e) Orders from undertaking activities which would be designated as significant new uses. The identities of 23 of the 28 chemical substances subject to this proposed rule have been claimed as confidential (per §§ 720.25) for a chemical substance covered by this action. Based on this, the Agency believes that it is highly unlikely that any of the significant new uses described in the regulatory text of this proposed rule are ongoing.

Therefore, EPA designates *[insert date of publication in the **Federal Register**]* as the cutoff date for determining whether the new use is ongoing. The objective of EPA's approach is to ensure that a person cannot defeat a SNUR by initiating a significant new use before the effective date of the final rule. In developing this proposed rule, EPA has recognized that, given EPA's general practice of posting proposed rules on its website a week or more in advance of **Federal Register** publication, this objective could be thwarted even before **Federal Register** publication of the proposed rule.

Persons who begin commercial manufacture or processing of the chemical substances for a significant new use identified as of that date would have to cease any such activity upon the effective date of the final rule. To resume their activities, these persons would have to first comply with all applicable SNUR notification requirements and wait until EPA has conducted a review of the notice, made an appropriate determination on the notice, and has taken such actions as are required with that determination.

## **VII. Development and Submission of Information**

EPA recognizes that TSCA section 5 does not require developing any particular new

information (e.g., generating test data) before submission of a SNUN. There is an exception: development of test data is required where the chemical substance subject to the SNUR is also subject to a rule, order or consent agreement under TSCA section 4 (see TSCA section 5(b)(1)).

In the absence of a TSCA section 4 test rule covering the chemical substance, persons are required only to submit information in their possession or control and to describe any other information known to or reasonably ascertainable by them (see 40 CFR 720.50). However, upon review of PMNs and SNUNs, the Agency has the authority to require appropriate testing. Unit IV. lists potentially useful information identified by EPA that would help characterize the potential health and/or environmental effects of the PMN/SNUN substance for all of the listed SNURs. EPA recognizes that the 2016 Lautenberg Amendments have led to modifications in our approach to testing requirements, including an increased consideration of alternatives to vertebrate testing. Descriptions of tests/information needs are provided for informational purposes only and EPA strongly encourages persons, before performing any testing, to consult with the Agency pertaining to protocol selection. Pursuant to TSCA section 4(h), which pertains to reduction of testing in vertebrate animals, EPA encourages consultation with the Agency on the use of alternative test methods and strategies (also called New Approach Methodologies, or NAMs), if available, to generate the potentially useful information. EPA encourages dialogue with Agency representatives to help determine how best the submitter can meet both the data needs and the objective of TSCA section 4(h). To access the OCSPP test guidelines referenced in this document electronically, please go to <http://www.epa.gov/ocspp> and select “Test Methods and Guidelines.” The Organisation for Economic Co-operation and Development test guidelines are available from the OECD Bookshop at <http://www.oecdbookshop.org> or SourceOECD at <http://www.sourceoecd.org>.

In certain of the TSCA section 5(e) Orders for the chemical substances that would be regulated under this proposed rule, EPA has established production limits in view of the lack of data on the potential health and environmental risks that may be posed by the significant new uses or increased exposure to the chemical substances. These limits cannot be exceeded unless the PMN submitter first submits the results of specified tests that would permit a reasoned evaluation of the potential risks posed by these chemical substances. Listings of the tests specified in the TSCA section 5(e) Orders are included in Unit IV. The proposed SNURs contain the same production limits as the TSCA section 5(e) Orders. Exceeding these production limits is defined as a significant new use. Persons who intend to exceed the production limit must notify the Agency by submitting a SNUN at least 90 days in advance of commencement of non-exempt commercial manufacture or processing and wait until EPA has conducted a review of the notice, made an appropriate determination on the notice, and has taken such actions as are required with that determination.

Any request by EPA for the testing described in the Orders was made based on EPA's consideration of available screening-level data, if any, as well as other available information on appropriate testing for the PMN substances. Further, any such testing/information request on the part of EPA that includes testing on vertebrates was made after consideration of available toxicity information, computational toxicology and bioinformatics, and high-throughput screening methods and their prediction models.

The potentially useful information listed in Unit IV. may not be the only means of addressing the potential risks of the chemical substance. EPA recommends that potential SNUN submitters contact EPA early enough so that they will be able to conduct the appropriate tests.

SNUN submitters should be aware that EPA will be better able to evaluate SNUNs which

provide detailed information on the following:

- Human exposure and environmental release that may result from the significant new use of the chemical substances.
- Information on risks posed by the chemical substances compared to risks posed by potential substitutes.

## **VIII. SNUN Submissions**

According to § 721.1(c), persons submitting a SNUN must comply with the same notification requirements and EPA regulatory procedures as persons submitting a PMN, including submission of test data on health and environmental effects as described in 40 CFR 720.50. SNUNs must be submitted on EPA Form No. 7710-25, generated using e-PMN software, and submitted to the Agency in accordance with the procedures set forth in 40 CFR 720.40 and § 721.25. E-PMN software is available electronically at <http://www.epa.gov/opptintr/newchems>.

## **IX. Economic Analysis**

EPA has evaluated the potential costs of establishing SNUN requirements for potential manufacturers and processors of the chemical substances subject to this proposed rule. EPA's complete economic analysis is available in the docket under docket ID number EPA-HQ-OPPT-2018-0650.

## **X. Statutory and Executive Order Reviews**

### *A. Executive Order 12866*

This proposed rule would establish SNURs for several new chemical substances that were the subject of PMNs and TSCA section 5(e) Orders. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993).

### *B. Paperwork Reduction Act (PRA)*

According to PRA (44 U.S.C. 3501 *et seq.*), an agency may not conduct or sponsor, and a person is not required to respond to a collection of information that requires OMB approval under PRA, unless it has been approved by OMB and displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the **Federal Register**, are listed in 40 CFR part 9, and included on the related collection instrument or form, if applicable.

The information collection requirements related to this proposed rule have already been approved by OMB pursuant to PRA under OMB control number 2070-0012 (EPA ICR No. 574). This action does not impose any burden requiring additional OMB approval. If an entity were to submit a SNUN to the Agency, the annual burden is estimated to average between 30 and 170 hours per response. This burden estimate includes the time needed to review instructions, search existing data sources, gather and maintain the data needed, and complete, review, and submit the required SNUN.

Send any comments about the accuracy of the burden estimate, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques, to the Director, Collection Strategies Division, Office of Environmental Information (2822T), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. Please remember to include the OMB control number in any correspondence, but do not submit any completed forms to this address.

### *C. Regulatory Flexibility Act (RFA)*

Pursuant to section 605(b) of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), the Agency hereby certifies that promulgation of this proposed SNUR would not have a



significant adverse economic impact on a substantial number of small entities. The requirement to submit a SNUN applies to any person (including small or large entities) who intends to engage in any activity described in the final rule as a “significant new use.” Because these uses are “new,” based on all information currently available to EPA, it appears that no small or large entities presently engage in such activities. A SNUR requires that any person who intends to engage in such activity in the future must first notify EPA by submitting a SNUN. Although some small entities may decide to pursue a significant new use in the future, EPA cannot presently determine how many, if any, there may be. However, EPA’s experience to date is that, in response to the promulgation of SNURs covering over 1,000 chemicals, the Agency receives only a small number of notices per year. For example, the number of SNUNs received was seven in Federal fiscal year (FY) 2013, 13 in FY2014, six in FY2015, 10 in FY2016, and 14 in FY2017, and only a fraction of these were from small businesses. In addition, the Agency currently offers relief to qualifying small businesses by reducing the SNUN submission fee from \$16,000 to \$2,800. This lower fee reduces the total reporting and recordkeeping of cost of submitting a SNUN to about \$10,116 for qualifying small firms. Therefore, the potential economic impacts of complying with this proposed SNUR are not expected to be significant or adversely impact a substantial number of small entities. In a SNUR that published in the **Federal Register** of June 2, 1997 (62 FR 29684) (FRL–5597–1), the Agency presented its general determination that final SNURs are not expected to have a significant economic impact on a substantial number of small entities, which was provided to the Chief Counsel for Advocacy of the Small Business Administration.

#### *D. Unfunded Mandates Reform Act (UMRA)*

Based on EPA's experience with proposing and finalizing SNURs, State, local, and Tribal

governments have not been impacted by these rulemakings, and EPA does not have any reasons to believe that any State, local, or Tribal government will be impacted by this action. As such, EPA has determined that this proposed rule would not impose any enforceable duty, contain any unfunded mandate, or otherwise have any effect on small governments subject to the requirements of UMRA sections 202, 203, 204, or 205 (2 U.S.C. 1501 *et seq.*).

*E. Executive Order 13132*

This proposed rule would not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999).

*F. Executive Order 13175*

This proposed rule would not have Tribal implications because it is not expected to have substantial direct effects on Indian Tribes. This proposed rule would not significantly nor uniquely affect the communities of Indian Tribal governments, nor would it involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000), do not apply to this action.

*G. Executive Order 13045*

This proposed rule is not subject to Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997), because this is not an economically significant regulatory action as defined by Executive Order 12866, and this action does not address environmental health or safety risks disproportionately affecting children.

#### *H. Executive Order 13211*

This proposed rule is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001), because this proposed rule is not expected to affect energy supply, distribution, or use and because this proposed rule is not a significant regulatory action under Executive Order 12866.

#### *I. National Technology Transfer and Advancement Act (NTTAA)*

In addition, since this proposed rule would not involve any technical standards, NTTAA section 12(d) (15 U.S.C. 272 note), does not apply to this action.

#### *J. Executive Order 12898*

This proposed rule does not entail special considerations of environmental justice related issues as delineated by Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

### **List of Subjects**

#### *40 CFR Part 721*

Environmental protection, Chemicals, Hazardous substances, Reporting and recordkeeping requirements.

Dated: February 27, 2019.

**Jeffery Morris,**

*Director, Office of Pollution Prevention and Toxics.*

Therefore, it is proposed that 40 CFR chapter I be amended as follows:

**PART 721--[AMENDED]**

1. The authority citation for part 721 continues to read as follows:

**Authority:** 15 U.S.C. 2604, 2607, and 2625(c).

2. Add § 721.11221 to subpart E to read as follows:

**§ 721.11221 Fatty acids, C16 and C18-unsaturated, methyl esters, chlorinated.**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substances identified as fatty acids, C16 and C18-unsaturated, methyl esters, chlorinated (PMN P-15-353, CAS No. 1642303-17-0) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in §721.80(k). It is a significant new use to manufacture the substance beyond three years.

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in §721.125(a) through (i) are applicable to manufacturers and processors of the substances.

(2) *Limitations or revocation of certain notification requirements.* The provisions of §721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of §721.1725(b)(1) apply to paragraph (a)(2)(i) of this section.

3. Add § 721.11222 to subpart E to read as follows:

**§ 721.11222 Chlorinated complex esters (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as chlorinated complex esters (PMN P-15-433) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in §721.80(k). It is a significant new use to manufacture the substance beyond three years.

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in §721.125(a) through (i) are applicable to manufacturers and processors of the substances.

(2) *Limitations or revocation of certain notification requirements.* The provisions of §721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of §721.1725(b)(1) apply to paragraph (a)(2)(i) of this section.

4. Add § 721.11223 to subpart E to read as follows:

**§ 721.11223 Sodium branched chain alkyl hydroxyl and branched chain alkenyl sulfonates (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as sodium branched chain alkyl hydroxyl and branched chain alkenyl sulfonates (P-16-186) is subject to reporting under this section for the significant new

uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (2)(i), (iv), (3), (When determining which persons are reasonable likely to be exposed as required for § 721.63(a)(1), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposures, where feasible), (6)(v), (vi), (particulate), (b)(concentration set at 1.0%), and (c).

(ii) *Hazard communication.* Requirements as specified in § 721.72 (a) through (e)(concentration set at 1.0%), (f), (g)(1)(i), (ii), (ix), (eye irritation), (2)(i), (v), (eye protection), (4)(i), (ii), (iii), and (5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(k). It is a significant new use to manufacture, process or use of the substance in a manner that results in inhalation exposure to vapor, dust, spray, mist, or aerosol.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a) through (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this significant new use rule.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(iii) of this section.

5. Add § 721.11224 to subpart E to read as follows:

**§721.11224 Spiro tetrafluoroborate (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as spiro tetrafluoroborate (PMN P-16-207) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in §721.63(a)(1), (2), (3), (4), (When determining which persons are reasonably likely to be exposed as required for §721.63 (a)(1) and (4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible), (a)(5)(respirators must provide a NIOSH assigned protection factor of at least 1000), (a)(6)(particulate), (b)(concentration set at 1.0%), and (c).

(A) As an alternative to the respirator requirements in paragraph (a)(2)(i) of this section, a manufacturer or processor may choose to follow the new chemical exposure limit (NCEL) provision listed in the TSCA section 5(e) Order for this substance. The NCEL is 0.2 mg/m<sup>3</sup> as an 8-hour time-weighted average. Persons who wish to pursue NCELs as an alternative to §721.63 respirator requirements may request to do so under §721.30. Persons whose §721.30 requests to use the NCELs approach are approved by EPA will be required to follow NCELs provisions comparable to those contained in the corresponding TSCA section 5(e) Order.

(B) [Reserved]

(ii) *Hazard communication.* Requirements as specified in §721.72(a) through (e)(concentration set at 1.0%), (f), (g)(1)(iv), (ix), (2)(i), (ii), (iii), (iv)(use respiratory protection,

or maintain workplace airborne concentrations at or below an 8-hour time-weighted average of 0.2 mg/m<sup>3</sup>, (v), (g)(5), alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in §721.80(f), (k), and (q).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in §721.125(a) through (i) and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of §721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of §721.1725(b)(1) apply to paragraph (a)(2)(iii) of this section.

6. Add § 721.11225 to subpart E to read as follows:

**§ 721.11225 2-Pyridinecarboxylic acid, 6-(4-chloro-2-fluoro-3-methoxyphenyl)-4,5-difluoro-, phenylmethyl ester.**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as 2-pyridinecarboxylic acid, 6-(4-chloro-2-fluoro-3-methoxyphenyl)-4,5-difluoro-, phenylmethyl ester (PMN P-16-246, CAS No. 1391033-38-7) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (2)(i), (iv), (3), (4), (When determining which persons are reasonably likely to be exposed as required for



§721.63(a)(1) and (4), engineering control measures (*e.g.*, enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.*, workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible), (a)(5)(respirators must provide a National Institute for Occupational Safety and Health assigned protection factor of at least 50), (a)(6)(i), (ii), (v), (vi), (b)(concentration set at 0.1%), and (c).

(ii) *Hazard communication*. Requirements as specified in § 721.72(a) through (e) (concentration set at 0.1%), (f), (g)(1)(i), (ii), (iv), (vi), (vii), (ix), (2)(i), (ii), (iii), (iv), (v), (3)(i), (ii), (4)(iii), and (5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80(k). It is a significant new use to manufacture the substance beyond nine months.

(iv) *Release to water*. Requirements as specified in § 721.90(a)(1), (b)(1), and (c)(1).

(b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125(a) through (i), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements*. The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section*. The provisions of §721.1725(b)(1) apply to paragraph (a)(2)(iii) of this section.

7. Add § 721.11226 to subpart E to read as follows:

**§ 721.11226 2-Pyridinecarboxylic acid, 4-amino-6-(4-chloro-2-fluoro-3-methoxyphenyl)-5-**

**fluoro-, phenylmethyl ester, hydrochloride (1:1).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as 2-pyridinecarboxylic acid, 4-amino-6-(4-chloro-2-fluoro-3-methoxyphenyl)-5-fluoro-, phenylmethyl ester, hydrochloride (1:1) (PMN P-16-516) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (2)(i), (iv), (3), (4), (When determining which persons are reasonably likely to be exposed as required for §721.63(a)(1) and (4), engineering control measures (*e.g.*, enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.*, workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible), (a)(5)(respirators must provide a National Institute for Occupational Safety and Health assigned protection factor of at least 50), (6)(i), (ii), (v), (vi), (b)(concentration set at 0.1%), and (c).

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (e)(concentration set 0.1%), (f), (g)(1)(i), (ii), (iv), (vi), (vii), (ix), (2)(i), (ii), (iii), (iv), (v), (3)(i), (ii), (4)(iii), and (5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(k). It is a significant new use to manufacture the substance beyond nine months.

(iv) *Release to water.* Requirements as specified in § 721.90(a)(1), (b)(1), and (c)(1).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section

except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(iii) of this section.

8. Add § 721.11227 to subpart E to read as follows:

**§ 721.11227 1,2,4-Benzenetricarboxylic acid, 1,2,4-trinonyl ester.**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as 1,2,4-benzenetricarboxylic acid, 1,2,4-trinonyl ester (P-16-271 and P-16-450, CAS No. 1817723-10-6) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been incorporated into a polymer matrix.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (2), (3), (When determining which persons are reasonable likely to be exposed as required for § 721.63(a)(1), engineering control measures (e.g. enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g. workplace policies and procedures) shall be considered and implemented to prevent exposures, where feasible), (a)(6)(particulate), (b)(concentration set at 1.0%), and (c).

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (e)(concentration set at 1.0%), (f), (g)(1)(i), (iv), (vi), (ix), (2)(i), (v), (4)(i), (ii), (iii), and (v).

Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, Commercial, and consumer activities.* Requirements as specified in § 721.80(f) and (p)(1,750,000 kilograms). It is a significant new use to use the substance other than as a plasticizer in wire and cable insulation.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

9. Add § 721.11228 to subpart E to read as follows:

**§ 721.11228 Aliphatic polyamines, polymers with bisphenol A and epichlorohydrin (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as aliphatic polyamines, polymers with bisphenol A and epichlorohydrin (PMN P-16-388) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted (cured).

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in §721.63(a)(1), (2)(i), (iii), (3), (When determining which persons are reasonably likely to be exposed as required for §721.63(a)(1) engineering control measures (e.g., enclosure or confinement of the operation,

general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible), (a)(6)(v), (vi), (particulate), (b)(concentration set at 1.0%) and (c).

(ii) *Hazard communication.* Requirements as specified in §721.72(a) through (e)(concentration set at 1.0%), (f), (g)(1)(i), (mucous membrane irritation), (lung irritation), (eye irritation), (g)(2)(i), (use gloves and eye protection), and (g)(5), alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in §721.80(k) and (o).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in §721.125(a) through (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of §721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of §721.1725(b)(1) apply to paragraph (a)(2)(iii) of this section.

10. Add § 721.11229 to subpart E to read as follows:

**§ 721.11229 Epoxy-amine adduct, methanesulfonates (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substances generically identified as epoxy-amine adduct, methanesulfonates (PMN P-16-489, PMN P-16-490, PMN P-16-491), are subject to reporting under this section for the significant

new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted (cured).

(2) The significant new uses are:

(i) *Hazard communication*. Requirements as specified in §721.72(a) through (e)(concentration set at 1.0%), (f), (g)(1)(ii), (2)(ii), (3)(i), (ii), (5), alternative hazard and warning statement that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(ii) *Industrial, commercial, and consumer activities*. Requirements as specified in §721.80(o). It is a significant new use to manufacture, process, or use the substances resulting in inhalation exposure to vapor, mist, or aerosols.

(iii) *Release to water*. Requirements as specified in §721.90(a)(4), (b)(4), and (c)(4) where  $N = 208$  ppb.

(b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping*. Recordkeeping requirements as specified in §721.125 (a), (b), (c), (f), (i), and (k).

(2) *Limitations or revocation of certain notification requirements*. The provisions of §721.185 apply to this section

11. Add § 721.11230 to subpart E to read as follows:

**§ 721.11230 Modified ethylene-vinyl alcohol copolymer (generic).**

(a) *Chemical substance and significant new uses subject to reporting*. (2) The chemical substance generically identified as modified ethylene-vinyl alcohol copolymer (P-16-509) is subject to reporting under this section for the significant new use described in paragraph (a)(2) of

this section. The requirements of this section do not apply to quantities of the substance after they have been reacted (cured).

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture, process, or use the substance with particle size less than 50 microns.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in §721.125(a), (b), (c), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of §721.185 apply to this section.

12. Add § 721.11231 to subpart E to read as follows:

**§ 721.11231 Cashew, nutshell liq., polymer with acid and halohydrin (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as cashew, nutshell liq., polymer with acid and halohydrin (PMN P-16-546) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in §721.63(a)(1), (2)(i), (iv), (3), (4), (When determining which persons are reasonably likely to be exposed as required for §721.63 (a)(1), (4) engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible),

(a)(5)(respirators must provide a National Institute for Occupational Safety and Health assigned protection factor (APF) of at least 50, or an APF of 1000 where the PMN substance has a use involving an application method that generates vapor, mist or aerosol), (6)(v), (vi), (particulate), and (c).

(ii) *Hazard communication.* Requirements as specified in §721.72(a) through (d), (f), (g)(1)(skin sensitization),(respiratory sensitization), (g)(2)(i), (ii), (iii), (iv), (v), (5), alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in §721.80(o).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in §721.125(a) through (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of §721.185 apply to this section.

13. Add § 721.11232 to subpart E to read as follows:

**§ 721.11232 Pentaerythritol ester of mixed linear and branched carboxylic acids (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as pentaerythritol ester of mixed linear and branched carboxylic acids (P-16-589) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:



(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (3), (When determining which persons are reasonable likely to be exposed as required for § 721.63(a)(1), engineering control measures (e.g. enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposures, where feasible), (a)(6)(particulate), (b)(concentration set at 1.0%), and (c).

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (e)(concentration set at 1.0%), (f), (g)(1)(iv), (v), (vi), (ix), (2)(i), (ii), (iii), (v), (4)(minimize release to water), and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(k). It is a significant new use to manufacture or process this substance in any manner that results in inhalation exposure.

(iv) *Release to water.* Requirements as specified in § 721.90(a)(4) and (b)(4), where N = 330 ppb.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this significant new use rule.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(iii) of this section.

14. Add § 721.11233 to subpart E to read as follows:

**§ 721.11233 Cashew nut shell liquid, branched polyester-polyether polyol (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as cashew nut shell liquid, branched polyester-polyether polyol (PMN P-17-116) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in §721.63(a)(1), (2)(i), (3), (When determining which persons are reasonably likely to be exposed as required for §721.63(a)(1), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible), (6)(particulate), (b)(concentration set at 0.1%) and (c).

(ii) *Hazard communication:* Requirements as specified in §721.72(a) through (e) (concentration set at 0.1%), (f), (g)(1)(sensitization), (g)(2)(i), (v), and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in §721.80(f), (p)(65,000 kg), and (y)(1). It is a significant new use to manufacture the PMN substance with greater than 0.1% weight residual cashew nut oil.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in §721.125(a) through (i).

(2) *Limitations or revocation of certain notification requirements.* The provisions of §721.185 apply to this section.

15. Add § 721.11234 to subpart E to read as follows:

**§ 721.11234 Methylene diphenyl diisocyanate terminated polyurethane resin (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as methylene diphenyl diisocyanate terminated polyurethane resin (PMN P-17-121) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in §721.63(a)(1), (2)(i), (iii), (iv), (3), (4), (When determining which persons are reasonably likely to be exposed as required for §721.63(a)(1) and (a)(4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible), (a)(5)(respirators must provide NIOSH assigned protection factor of at least 50), (a)(6)(v), (vi), (particulate), (b)(concentration set at 1.0%) and (c).

(ii) *Hazard communication.* Requirements as specified in §721.72(a) through (e)(concentration set at 1.0%), (f), (g)(1)(i), (ii), (asthma), (g)(2)(i), (ii), (iii), (iv), (v), and (g)(5), alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture, process, or use the substance for consumer use or for commercial uses that could introduce the substance into a consumer setting. It is a significant new use to manufacture the

substance without conducting medical surveillance as specified in the Order. It is a significant new use to use the substance in a spray application that results in inhalation exposure to a vapor, dust, mist, spray, or aerosol.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in §721.125(a) through (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of §721.185 apply to this section.

16. Add § 721.11235 to subpart E to read as follows:

**§ 721.11235 2-Furancarboxylic acid, tetrahydro-.**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as 2-furancarboxylic acid, tetrahydro- (PMN P-17-328, CAS No. 16874-33-2) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in §721.63(a)(1), (2)(i), (iii), (iv), (3), (4), (When determining which persons are reasonably likely to be exposed as required for §721.63(a)(1) and (4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible), (a)(5)(respirators must provide a National Institute for Occupational Safety and Health assigned protection factor of at least 50), (a)(6)(v), (vi), (particulate), (b)(concentration set at

1.0%), and (c).

(ii) *Hazard communication.* Requirements as specified in §721.72(a) through (e)(concentration set at 1.0%), (f), (g)(1)(vi), (severe eye irritation), (blood effects), (immunotoxicity), (g)(2)(i), (ii), (iii), (v), (eye protection), (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in §721.80(f).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in §721.125(a) through (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of §721.185 apply to this section.

17. Add § 721.11236 to subpart E to read as follows:

**§ 721.11236 Substituted heteromonocycle, homopolymer, alkyl substituted carbamate, substituted alkyl ester, substituted heteromonocycle, homopolymer, alkyl substituted carbamate, substituted alkyl ester (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as substituted heteromonocycle, homopolymer, alkyl substituted carbamate, substituted alkyl ester, substituted heteromonocycle, homopolymer, alkyl substituted carbamate, substituted alkyl ester (PMN P-17-373) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of the

Order do not apply to quantities of the substance after they have been completely reacted (cured).

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in §721.63(a)(1), (2)(i), (3), (4), (When determining which persons are reasonably likely to be exposed as required for §721.63(a)(1) and (a)(4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible), (a)(5)(respirators must provide a National Institute for Occupational Safety and Health assigned protection factor of at least 50), (a)(6)(v), (vi), (particulate), (b)(concentration set at 0.1%) and (c).

(ii) *Hazard communication.* Requirements as specified in §721.72(a) through (e)(concentration set at 0.1%), (f), (g)(1)(i), (vii), (ix), (sensitization), (systemic effects), (a)(2)(i), (ii), (iii), (v), (a)(5), alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in §721.80(f). It is a significant new use to manufacture the substance unless the number average molecular weight is greater than or equal to 1000 daltons. It is a significant new use to use the substance other than as an ultraviolet curable coating resin.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in §721.125(a) through (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of

§721.185 apply to this section.

18. Add § 721.11237 to subpart E to read as follows:

**§ 721.11237 Polysiloxanes, di alkyl, substituted alkyl group terminated, alkoxyated, reaction products with alkanoic acid, isocyanate substituted-alkyl carbomonocycle and polyol (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as polysiloxanes, di alkyl, substituted alkyl group terminated, alkoxyated, reaction products with alkanoic acid, isocyanate substituted-alkyl carbomonocycle and polyol (PMN P-17-374) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of the Order do not apply to quantities of the PMN substance after they have been completely reacted (cured).

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in §721.63(a)(1), (2)(i), (3), (4), (When determining which persons are reasonably likely to be exposed as required for §721.63(a)(1) and (a)(4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures.) shall be considered and implemented to prevent exposure, where feasible), (a)(5)(respirators must provide a NIOSH assigned protection factor of at least 50), (a)(6)(v), (vi), (particulate), (b)(concentration set at 0.1%) and (c).

(ii) *Hazard communication.* Requirements as specified in §721.72(a) through (e)(concentration set at 0.1%), (f), (g)(1)(i), (vii), (ix), (sensitization), (systemic effects), (g)(2)(i), (ii), (iii), (v), (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in §721.80(f). It is a significant new use to import the substance with more than 0.1% residual isocyanate. It is a significant new use to import the substance at a number average molecular weight less than 1000 daltons. It is a significant new use to use the substance other than as an ultraviolet curable coating resin.

(iv) *Release to water.* Requirements as specified in §721.90(a)(4), (b)(4), and (c)(4) where  $N = 110$ .

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in §721.125(a) through (k) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of §721.185 apply to this section.

19. Add § 721.11238 to subpart E to read as follows:

**§ 721.11238 Substituted carbomonocycle, polymer with substituted heteromonocycle and substituted polyalkylene glycol (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as substituted carbomonocycle, polymer with substituted heteromonocycle and substituted polyalkylene glycol (PMN P-18-17) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been reacted (cured).

(2) The significant new uses are:



(i) *Protection in the workplace.* Requirements as specified in §721.63(a)(1), (2)(i), (iii), (iv), (3), (4), (When determining which persons are reasonably likely to be exposed as required for §721.63(a)(1) and (a)(4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible), (a)(5)(respirators must provide a National Institute for Occupational Safety and Health assigned protection factor of at least 1000), (a)(6)(particulate), (b)(concentration set at 0.1%) and (c).

(ii) *Hazard communication.* Requirements as specified in §721.72(a) through (e)(concentration set at 0.1%), (f), (g)(1)(i), (ii), (iii), (iv), (v), (vi), (vii), (ix), (irritation to eyes, lungs, and mucus membranes), (g)(2)(i), (ii), (iii), (iv), (v), (avoid eye contact), (g)(5), alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in §721.80(f), It is a significant new use to import the substance if the average molecular weight is less than or equal to 1000 daltons, more than 10% is less than 500 daltons, or more than 25% is less than 1000 daltons. It is a significant new use to use the substance other than for primer coating for corrosion protection.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in §721.125(a) through (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of

§721.185 apply to this section.

20. Add § 721.11239 to subpart E to read as follows:

**§721.11239 Alkanedioic acid, polymers with alkanolic acid-dipentaerythritol reaction products, substituted alkanedioic acid, substituted alkanolic acid, isocyanato-(isocyanatoalkyl)-alkyl substituted carbomonocycle and alkyl substituted alkanediol (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as alkanedioic acid, polymers with alkanolic acid-dipentaerythritol reaction products, substituted alkanedioic acid, substituted alkanolic acid, isocyanato-(isocyanatoalkyl)-alkyl substituted carbomonocycle and alkyl substituted alkanediol (PMN P-18-40) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been reacted (cured).

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in §721.63(a)(1), (2)(i), (iii), (iv), (3), (4), (When determining which persons are reasonably likely to be exposed as required for §721.63(a)(1) and (4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible), (a)(5)(respirators must provide a National Institute for Occupational Safety and Health assigned protection factor of at least 1000), (a)(6)(particulate), and (c).

(ii) *Hazard communication.* Requirements as specified in §721.72(a) through (d), (f), (g)(1)(i), (vii), (ix), (irritation to eyes, lungs, and mucous membranes), (dermal sensitization),

(respiratory sensitization), (g)(2)(i), (ii), (iii), (iv), (v), (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in §721.80(f). It is a significant new use to import the substance if the number average molecular weight is less than or equal to 1000 daltons or greater than 20% of the acid moiety. It is a significant new use to use the substance other than as a binder for ultraviolet curable coating resins.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in §721.125(a) through (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of §721.185 apply to this section.

21. Add § 721.11240 to subpart E to read as follows:

**§ 721.11240 Substituted carbomonocycle, polymer with diisocyanatoalkane, substituted alkylacrylate blocked (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as substituted carbomonocycle, polymer with diisocyanatoalkane, substituted alkylacrylate blocked (PMN P-18-46) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in §721.63(a)(1), (2)(i), (iii),

(iv), (3), (4), (When determining which persons are reasonably likely to be exposed as required for §721.63(a)(1) and (a)(4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible), (a)(5)(respirators must provide a National Institute for Occupational Safety and Health assigned protection factor of at least 1000), (a)(6)(particulate), (b)(concentration set at 0.1%) and (c).

(ii) *Hazard communication.* Requirements as specified in §721.72(a) through (e)(concentration set at 0.1%), (f), (g)(1)(i), (iv), (v), (vii), (ix), (irritation to eyes, lungs, and mucus membranes), (dermal and respiratory sensitization), (g)(2)(i), (ii), (iii), (iv), (v), (avoid eye contact), (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in §721.80(f). It is a significant new use to import the substance if the average molecular weight is less than or equal to 1390 daltons, more than 11% is less than 500 daltons, or more than 30% is less than 1000 daltons. It is a significant new use to use the substance other than as an ultraviolet curable resin.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in §721.125(a) through (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of §721.185 apply to this section.

22. Add § 721.11241 to subpart E to read as follows:

**§721.11241 1,2-Ethanediol, 1,2-dibenzoate.**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as 1,2-ethanediol, 1,2-dibenzoate (PMN P-18-47, CAS No. 94-49-5) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely entrained in cured resin.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in §721.63(a)(1), (2), (3), (4), (When determining which persons are reasonably likely to be exposed as required for §721.63(a)(1) and (4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible), (a)(5)(respirators must provide a National Institute for Occupational Safety and Health assigned protection factor of at least 25), (a)(6), (v), (vi), (particulate), (b)(concentration set at 1.0%), and (c).

(ii) *Hazard communication.* Requirements as specified in §721.72(a) through (e)(concentration set at 1.0%), (f), (g)(1)(iii), (iv), (vi), (viii), (ix), (blood effects), (g)(2)(i), (ii), (iv), (v), (3)(i), (ii), (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in §721.80(f). It is a significant new use to use the substance other than as a phlegmatizer (stabilizer for compounds susceptible to detonation) for peroxides for use with polyester and vinyl ester

resins as well as with curable unsaturated polyester and methacrylic resins.

(iv) *Release to water.* Requirements as specified in §721.90(a)(4), (b)(4), and (c)(4) where  $N = 10$ .

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in §721.125(a) through (i) and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of §721.185 apply to this section.

23. Add § 721.11242 to subpart E to read as follows:

**§721.11242 Alkenoic acid, reaction products with polymers with isocyanatoalkane and substituted alkenoic acid, substituted monoacrylate alkenoate-blocked (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as alkenoic acid, reaction products with polymers with isocyanatoalkane and substituted alkenoic acid, substituted monoacrylate alkenoate-blocked (PMN P-18-51) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been reacted (cured).

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in §721.63(a)(1), (2)(i), (iii), (iv), (3), (4), (When determining which persons are reasonably likely to be exposed as required for §721.63(a)(1) and (4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace

policies and procedures) shall be considered and implemented to prevent exposure, where feasible), (a)(5)(respirators must provide a National Institute for Occupational Safety and Health assigned protection factor of at least 1000), (a)(6)(particulate), and (c).

(ii) *Hazard communication*. Requirements as specified in §721.72(a) through (d), (f), (g)(1)(i), (ix), (irritation to eyes, lungs, and mucous membranes), (dermal sensitization), (respiratory sensitization), (g)(2)(i), (ii), (iii), (iv), (v), (avoid eye contact), (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities*. Requirements as specified in §721.80(f). It is a significant new use to use the substance other than as a waterborne ultraviolet curable coating resin binder for inkjet, ink, or overprint varnish. It is a significant new use to import the substance with greater than 24% of the branched alkyl acid moiety content. It is a significant new use to import the substance with greater than 0.1% isocyanate content.

(iv) *Release to water*. Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) where  $N = 660$ .

(b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping*. Recordkeeping requirements as specified in §721.125(a) through (i) and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements*. The provisions of §721.185 apply to this section.

24. Add § 721.11243 to subpart E to read as follows:

**§ 721.11243 Aromatic dicarboxylic acid, compd. with alkane diamines, polymer**

**with alkane diamine and alkane dicarboxylic acid (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as aromatic dicarboxylic acid, compd. with alkane diamines, polymer with alkane diamine and alkane dicarboxylic acid (P-18-71) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, Commercial, and consumer activities.* It is a significant new use to manufacture the substance with particle size less than 10 microns.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c) and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this significant new use rule.

25. Add § 721.11244 to subpart E to read as follows:

**§ 721.11244 Aromatic dicarboxylic acid, compd. with alkyl diamines, homopolymer (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as aromatic dicarboxylic acid, compd. with alkyl diamines, homopolymer (P-18-79) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new use is:

(i) *Industrial, Commercial, and consumer activities.* It is a significant new use to



manufacture the substance with particle size less than 10 microns.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c) and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this significant new use rule.

26. Add § 721.11245 to subpart E to read as follows:

**§ 721.11245 Aspartic acid, tallow modified diester (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as aspartic acid, tallow modified diester (PMN P-18-82) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in §721.63(a)(1), (2)(i), (iii), (3), (When determining which persons are reasonably likely to be exposed as required for §721.63(a)(1), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible), (b)(concentration set at 1.0%), and (c).

(ii) *Hazard communication.* Requirements as specified in §721.72(a) through (e)(concentration set at 1.0%), (f), (g)(1)(i), (ii), (iv), (2)(i), (ii), (v), (3)(i), (ii), (4)(iii)(above concentration of 1 part per billion (ppb), (g)(5). Alternative hazard and warning statements that

meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in §721.80(g). It is a significant new use to manufacture, process, or use the substance that results in inhalation exposure. It is a significant new use to manufacture, process and use the substance other than as stated in the PMN.

(iv) *Disposal.* Residuals must be recycled back into the process as stated in the PMN.

(v) *Release to water.* Requirements as specified in §721.90(a)(4), (b)(4), (c)(4) where N = 1.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in §721.125(a) through (k) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of §721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of §721.1725(b)(1) apply to paragraphs (a)(2)(iii) and (iv) of this section.

27. Add § 721.11246 to subpart E to read as follows:

**§ 721.11246 Substituted alkanediol, polymer with heteromonocycles, alkenoate, metal complexes (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as substituted alkanediol, polymer with heteromonocycles, alkenoate, metal complexes (PMN P-18-130) is subject to reporting under this section for the

significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been reacted (cured).

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in §721.63(a)(1), (2)(i), (iii), (3), (4), (When determining which persons are reasonably likely to be exposed as required for §721.63(a)(1), (4) engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible), (a)(5)(respirators must provide a National Institute for Occupational Safety and Health assigned protection factor (APF) of at least 50, or if spray applied an APF of 1000), (a)(6)(v), (vi), (particulate), and (c).

(ii) *Hazard communication.* Requirements as specified in §721.72(a) through (d), (f), (g)(1)(i), (sensitization), (mutagenicity), (g)(2)(i), (ii), (iii), (iv), (v), (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in §721.80(f). It is a significant new use to use the substance other than as an adhesion promoter for industrial applications.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in §721.125(a) through (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of

§721.185 apply to this section.

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